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| 10/677,132 | 10/01/2003 | Fred J. Stutzenberger | CXU-382 | 3896 |

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DORITY & MANNING, P.A.
POST OFFICE BOX 1449
GREENVILLE, SC 29602-1449

| EXAMINER |
|---|
| AUDET, MAURY A |

| ART UNIT | PAPER NUMBER |
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| 1654 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| *Office Action Summary* | **Application No.**<br>10/677,132 | **Applicant(s)**<br>STUTZENBERGER ET AL. | |
|---|---|---|---|
| | **Examiner**<br>MAURY AUDET | **Art Unit**<br>1654 | |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 23 April 2008.
2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 46-69 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) 46-69 is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on 01 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/04, 6/2/05, 6/04/05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election without traverse of Group III, new claims 46-69, as drawn to the elected invention (NOT species; see below) in the reply filed on 4/23/08 is acknowledged:

> the following nanoparticle comprising a hydrophobic polymeric core, a hydrophilic linking agent bound to said core, and a biofunctional material comprising a binding site that can bind adhesins on the surface of an enteropathogenic microorganism:

1. hydrophobic polymeric *core* - **polystyrene** (see, e.g., ¶[008], p. 2 of the captioned application);

2. hydrophilic polymeric *linking agent* - **polyethylene glycol** (see, e.g., ¶[009], p. 2 of the captioned application);

3. *biofunctional material* including a binding site that can bind adhesins on the surface of an enteropathogenic microorganism - **a mono- or polysaccharide** (see, e.g., ¶[010], p. 3 of the captioned application).

> The pending claims are directed to a method for agglomerating biologically active microorganisms comprising contacting a first enteropathogenic microorganism with a first nanoparticle, one example of which is identified above as required by the Examiner; binding a first adhesin of the first enteropathogenic microorganism to the first binding site of the biofunctional material to form a nanoparticle/microorganism complex; and binding a second adhesin of a second enteropathogenic microorganism to a second binding site of the biofunctional material of the nanoparticle/microorganism complex. All of the pending claims are generic to the above-identified composite

As noted in the Interview Summary (10/29/07 mailing) as to the elected invention:

Applicant telephoned to discuss the outstandinq restriction requirement generally and *to clarify that the election of a fully defined structure (or at least substantial core as to the relevant structure therein (biofunctional material) as to the composition is an election of the invention as to the elected Group*, rather than a species election. Applicant's interpretation is correct."

## *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 46-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franzen et al. (US 2003/0147966 A1).

Franzen et al. teach that nanoparticles may comprise any one or more of the elected elements of polystyrene, PEG, and/or mono/polysaccharides:

> [0065] The present invention describes a nanoparticle delivery vehicle that can be used with a variety of subjects including warm blooded animals, particularly mammals, including humans, dogs, cats and other small animals, and farm animals. Additionally, the nanoparticles of the present invention can be used with prokaryotic and eukaryotic microorganisms and with in vitro cultures. The nanoparticle delivery vehicle of the present invention can be used as a diagnostic agent in all of the above subjects, as well as in the capacity of a therapeutic agent. There is no limitation on the type of biologically active structure the subject to which a nanoparticle of the present invention can be introduced. See, e.g., U.S. Pat. Nos. 5,783,263 and 6,106,798. See also, Colloidal Drug Delivery Systems, (1994) (Kreuter, ed.), Marcel Dekker, Inc., New York, pp 219-342; Kreuter, (1994) Eur. J. Drug Metab. Ph. 3: 253-56.

> [0071] The nanoparticle, which can also be referred to as a scaffold, of a nanoparticle delivery vehicle can comprise a variety of inorganic materials including, but not limited to, metals, semi-conductor materials or ceramics. Preferred metal-based compounds for the manufacture of nanoparticles include titanium, titanium dioxide, tin, tin oxide, silicon, silicon dioxide, iron, iron.sup.IIII oxide, silver, gold, copper, nickel, aluminum, steel, cobalt-chrome alloys, cadmium (preferably cadmium selenide) and titanium alloys. Preferred ceramic materials include brushite, tricalcium phosphate, alumina, silica, and zirconia. The nanoparticle can be made from organic materials including carbon (diamond). Preferred polymers include polystyrene, silicone rubber, polycarbonate, polyurethanes, polypropylenes, polymethylmethacrylate, polyvinyl chloride, polyesters, polyethers, and polyethylene. Biodegradable, biopolymer (e.g. polypeptides such as BSA, polysaccharides, etc.), other biological materials (e.g. carbohydrates), and/or polymeric compounds are also suitable for use as a nanoparticle scaffold. Gold is especially preferred due to its well-known reactivity profiles and biological inertness.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrive at a nanoparticles comprising the well-known elements above known to bind other agents in Franzen et al., because nanoparticles comprising any one or more of the elected elements of polystyrene, PEG, and/or mono/polysaccharides are well known in the art, as advanteously taught by Franzen et al., and the binding of any molecule, including microorganisms (even more than one, e.g. agglomerating) is merely a matter of routine optimization of known methods for binding other agents with nanoparticles, depending on the agent to be bound.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

### *Claim Rejections - 35 USC § 112 2nd*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 46-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "agglomerating" in claim 46 is a relative term which renders the claim indefinite. The term "agglomerating" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. E.g. how many constitutes agglomerating? And what is the size of the nanoparticle in order to bind said 1 or more microorganisms?

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA 9/15/08

/Maury Audet/

Examiner, Art Unit 1654

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654